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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,522	04/16/2004	Geert Plaetinck	D0590.70011US02	2890

23628 7590 08/01/2008
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BOSTON, MA 02210-2206

EXAMINER

SHIN, DANA H

ART UNIT	PAPER NUMBER
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1635

MAIL DATE	DELIVERY MODE
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08/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/826,522	Applicant(s) PLAETINCK ET AL.	
	Examiner DANA SHIN	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-41, 70-74 and 80-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-41, 70-74 and 80-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

This Office action is in response to the communications filed on June 6, 2008.

Currently, claims 30-41, 70-74, and 80-83 are pending and under examination on the merits.

The following rejections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Response to Arguments

Applicant's arguments with respect to claims 30-41, 70-74, and 80-83 have been considered but are moot in view of the new ground(s) of rejection. See below.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 30-41, 70-74, and 80-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fire et al. (WO 99/32619 A1, citation of record) in view of Noren et al. (US 5,691,140), Conkling et al. (US 5,459,252), and Talkad et al. (*Journal of Bacteriology*, 1978, 135:528-541, citation of record).

The claims are drawn to a micro-organism comprising an expression vector comprising two promoters that flank a DNA sequence, wherein the micro-organism is *E.coli*, or a nematode, or a yeast, wherein the promoters are identical T7 promoters or different promoters, or root-specific promoters.

Fire et al. teach *C. elegans* comprising an expression vector having an RNA polymerase promoter selected from T7, T3, and SP6, thereby producing double-stranded RNA in the *C.*

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elegans in vivo. They teach that the micro-organism comprising the expression vector can be any organism including plant, animal, protozoan, virus, *E. coli*, yeast, and parasitic nematode. See pages 7, 12-13, 17-18, and 26. It is noted that all of the teachings are also disclosed in their priority document U.S. 60/068,562. For example, the disclosure of 60/068,562 teaches that the target organism can be any organism including plants, animals, fungi, and yeasts and that the double-stranded RNA can be synthesized *in vivo* in the organism by utilizing an expression vector comprising an RNA polymerase promoter such as T3, T7, and SP6. See pages 7, 10-11. Fire et al. in view of the disclosure of 60/068,562 do not teach an expression vector comprising two promoters wherein the promoters are root-specific promoters.

Noren et al. teach bidirectional expression vectors comprising two opposing RNA polymerase promoters, wherein the promoters are of the same kind (e.g., T7 and T7) or of different kinds (e.g., SP6 and T7). They teach that such bidirectional expression vectors comprising two promoters in opposite direction allow efficient transcription of either strand of the inserted piece of RNA sequence. For example, they show that the sense strand (or top strand) of the inserted RNA sequence is transcribed by the promoter located at the 5' of the sense strand (that is, the promoter having a 'right' directionality), while the antisense strand (or bottom strand) is transcribed by the promoter located at the 3' of the sense strand (that is, the promoter having a 'left' directionality). Further, the bidirectional vectors are manufactured by a commercial vendor New England Biolabs, Inc. See columns 1-2; claims 1-2; Figures 1, 4B, 6-7.

Conkling et al. teach that a root-specific promoter RB7 in an expression vector allows root-specific transcription and expression of an exogenous nucleotide sequence in a plant cell. See columns 5-8 and claims 1-13.

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Talkad et al. teach *E. coli* strains that are deficient in RNase III. They teach that RNase III cleaves bacteriophage T7 RNAs as well as double-stranded RNAs.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the expression vector construct of Fire et al. by incorporating the teachings of Noren et al. and Conkling et al., so as to produce an organism comprising an expression vector that allows desired transcription and expression of the double-stranded RNA within the organism.

One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success, because the skilled artisan would have recognized the benefit of using the bidirectional promoter expression construct of Noren et al. such that he/she can generate efficient transcription of both strands of the dsRNA of Fire et al. for RNA interference, and because the skilled artisan would have also recognized the benefit of utilizing the root-specific promoter of Conkling et al. for generating root-specific transcription and RNAi activity of the dsRNA of Fire et al. In addition, one of ordinary skill in the art would have been further motivated to make an *E. coli* bacteria that is deficient in RNase III of Talkad et al. comprising the modified expression vector as described above, because the use of RNase III-negative bacterial strain would prevent cleavage of promoters and the double-stranded RNA molecule, as taught by Talkad et al. Since all the necessary materials (e.g., bidirectional expression vector construct, root-specific promoter, RNase III-negative *E. coli* strain) were known and available in the art at the time of the invention, and since making the instantly claimed invention by incorporating and combining the teachings of the prior art was within the technical grasp of one of ordinary skill in the art at the time of the invention, the skilled artisan would have had a reasonable expectation of success

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in arriving at the claimed invention. In light of the above, the claimed invention taken as a whole would have been *prima facie* obvious at the time of filing.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, from 7am-3:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

/J. E. Angell/
Primary Examiner, Art Unit 1635

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